PROSTHETIC REPLACEMENT OF THE URINARY VESICAL SPHINCTER

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by

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I INTRODUCTION

Efficient artificicial restoration of the urinary vesical sphincter has been an ideal of surgeons and urologists for many years. In the treatment of some tumors of the bladder, prostate, rectum, and uterus as well as certain congenital urological anomalies, it may be necessary not only to substitute the impaired urethra with a new urinary conduit, but also to restore the vesical sphincter. For this purpose, numerous operations have been reported, but most of them are unsatisfactory.

JOHNSON proposed the following criteria for the artificial bladder.

1. Continence and voluntary control of both urine and feces.
2. Complete separation of the urinary and fecal streams.
3. Functional reservoir without urinary reabsorption.
4. No artificial orifice in an unnatural site.
5. Conditions permitting total cystectomy.
6. Accessible to easy cystoscopic examination.

It seems that there have been few methods to satisfy these conditions.

From the author's laboratory, KIMURA et al. reported a new plastic operation of the posterior urethra utilizing the ileal segment as substitute, and gave a solution, to some extent, to the problem of urinary control.

The author intended to restore the vesical sphincter with plastic materials, designing several types of the valve reactable with the intravesical pressure, and applied them to the experimental animals and also to a clinical case.

II MATERIALS AND METHODS

(1) Kinds and Shapes of the Artificial Valves.

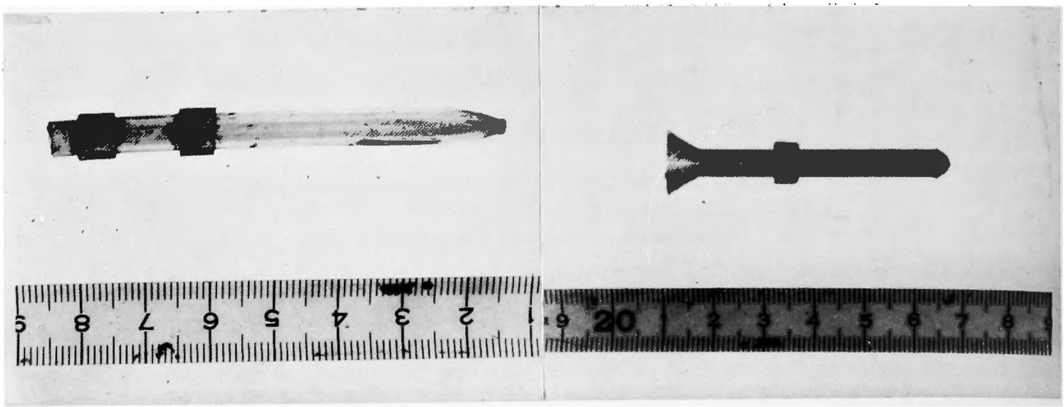
Artificial valves used for this study were as follows:

(A) Straight Valve.
  (a) Straight type.
  (b) Funnel type.
(B) Balloon Valve.
  (a) Thin wall balloon.
  (b) Thick wall balloon.

(A) Straight Valve.

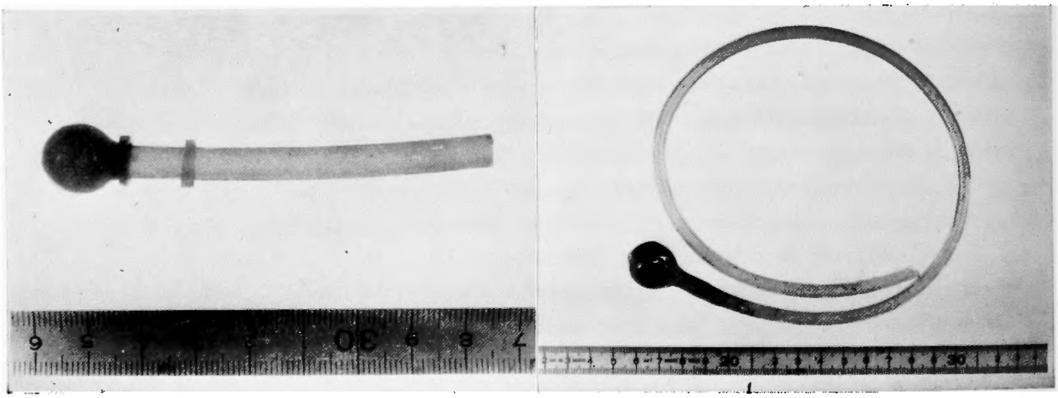
This valve was made of a plastic tube closed at one end and fitted with a small

Fig. 1 Straight valve.



(a) Straight type. (b) Funnel type.

Fig. 2 Balloon valve



(a) Thin wall balloon. (b) Thick wall balloon.

slit at its lateral border (Fig. 1). The valve was fixed with a fabric tape in the following way: the open end was placed at the internal vesical orifice and the rest of the tube with blind end was in the urethra.

The straight valves were divided into two groups: the straight type (Fig. 1, a) and the funnel type (Fig. 1, b). The latter was made from silicone (Phycon) and the former was made of the vinyl chloride tube (Table I).

(B) Balloon Valve.

This valve was consisted of a tube and a balloon at its end (Fig. 2). The balloon was equipped with one slit at the top. This valve was fixed with a fabric tape at the vesical neck in the following way: the balloon was placed in the bladder and the tube in the urethra.

The balloon valves were also divided into two groups according to the thickness of the balloon: the thin wall balloon (Fig. 2, a) and the thick wall balloon (Fig. 2, b). These valves were made from rubber latex and some from silicone (Silastic RTV 501). Most of balloons were coated with silicone (Silastic RTV 731), but a few of them

Table I Straight Valves.

Dog No.	Materials of Valve	Diameter of Tube Outside/Inside (mm)	Length of Tube (cm)	Opening Pressure (cm H_2O)
S- 4	Vinyl Chloride	5/3	4.3	24
S- 5	Vinyl Chloride	5/3	4.5	21
S- 7	Vinyl Chloride	5/3	6.5	26
S- 8	Vinyl Chloride	5/3	4.5	16
S-13	Vinyl Chloride	6/4	6.3	17
S-14	Vinyl Chloride	6/4	6.5	14
S-15	Vinyl Chloride	6/4	5.8	10
S-16	Vinyl Chloride	6/4	7.0	3
S-17	Vinyl Chloride	6/4	7.8	0
S-18	Silicone	6/4	5.0	15
S-19	Silicone	6/4	5.0	0
S-20	Vinyl Chloride	6/4	7.0	10
S-21	Vinyl Chloride	6/4	6.2	9
S-22	Silicone	6/4	5.0	0
S-23	Vinyl Chloride	6/4	7.0	0
S-24	Silicone	6/4	5.0	0
S-25	Vinyl Chloride	6/4	6.3	0

Table II Balloon Valves.

Dog No.	Materials of Valve		Diameter of Balloon (mm)	Valve Pressure (cmH_2O)	
	Balloon	Tube		Opening	Closing
B- 1	Rubber	Vinyl Chloride	10	32	11
B- 2	Rubber	Vinyl Chloride	12	23	7
B- 3	Rubber	Vinyl Chloride	12	18	8
B- 4	Rubber	Vinyl Chloride	12	17	2
B- 5	Silicone	Vinyl Chloride	12	29	6
B- 6	Silicone	Silicone	12	27	8
B- 7	Silicone	Silicone	12	25	11
B- 8	Silicone	Silicone	12	27	10
B- 9	Silicone	Silicone	12	35	15
B-10	Silicone	Silicone	12	15	3
S-11	Rubber	Silicone	12	103	28
S-14	Rubber	Silicone	18	92	25
S-15	Rubber	Silicone	12	125	37

were used without coating (Table II).

(2) Experimental Animals.

Adult female mongrel dogs, weighning 7 to 16 kg, were used.

(3) Insertion and Fixation of the Artificial Valves.

All of the experimental animals were anesthetized with Sodium-Pentobarbital

(Nembutal). After the suprapubic midline incision (Fig. 3, a), peritoneum over the bladder neck was longitudinally split and the fatty tissue was swept off from the bladder neck by blunt dissection. Then, the fixing tape, made of Tetron fabrics or Polyvinyl formal sponge, was set around the bladder neck for fixation of the valve. Next, the anterior bladder wall was opened, and the valve was passed into the bladder neck (Fig. 3, b). After closing the bladder wall with interrupted fine silk sutures, the fixing tape was sutured together around the urethra (Fig. 3, c). Bleeding and urinary leakage was promptly controlled for the prevention of clot formation in the bladder or of abdominal contamination. Immediately after the operation, 1.0 gm of Dihydro-Streptomycin and 200,000 units of Procain Penicillin were injected, and antibiotics were continued for 3 to 5 days postoperatively.

Fig. 3

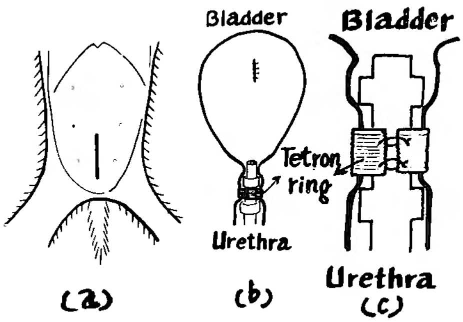
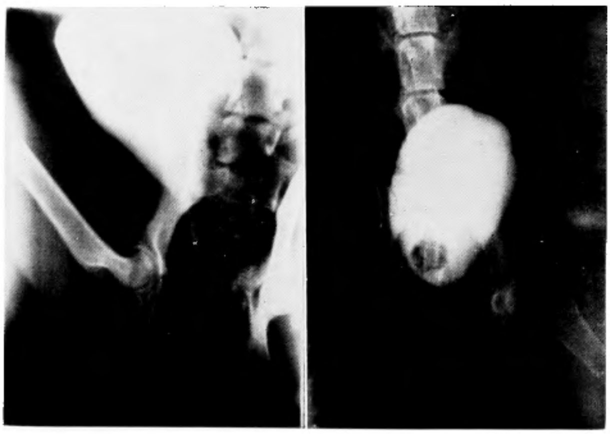


Fig 4 Cystogram



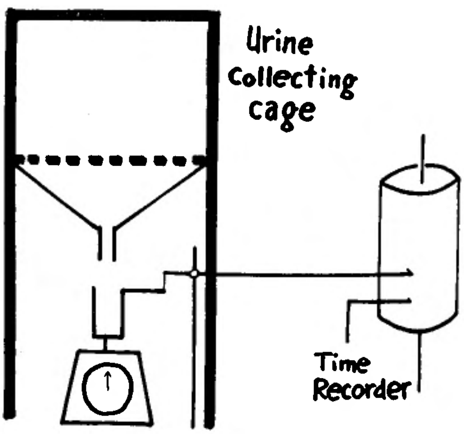
(a) Straight valve. (b) Balloon valve.

Cystograms were showed at Fig. 4, a and b.

(4) Urological Examinations and Tests.

(i) Cystometry: This examination was performed on animals under slight intravenous anesthesia with Sodium-Pentobarbital. Cystometry was repeated until the animal was sacrificed. Postoperatively, an urethral catheter was inserted directly into the bladder, because its insertion

Fig 5 Urofometer.



through the urethra was not possible on account of the mechanism of these valves. After the bladder and abdominal wall was closed, cystometry was performed.

(ii) Measurement of urinary flow rate and residual urine volume: Urinary flow rate was measured quantitatively with the uroflometer designed by DRAKE (Fig. 5). Since the dog in the urine collecting cage retained the urine and did not void for a long time, she had to be forced to void with injection of Besacholine (0 25 mg/kg). The several days later, the animal was sacrificed immediately after urination, then the residual urine volume was measured.

(iii) Renal function test: As to the postoperative state of renal functicns, serum urea-nitrogen was measured by means of Diacetyl Monoxime method using photoelectric colorimeter.

(iv) Patho-histological examination: By the gross examination, urinary salts or calculi were searched for in the urinary tract or on the surface of the valve. Histological survey was also performed on the bladder neck, bladder wall and kidney with special

Table III Straight Valve Group

Dog No.	Weight (kg)	Length of Survival (days)	Cause of Death	State of Urination	Flow Rate (cc/sec)	Residual Urine (cc)	NOTES
T-1	8	39	S.	I.			
T-3	11	338	S.	I.→D.		50	Tube dislocated into bladder. Urinary salts.
S-4	10	88	S.	N.→D.		150	Fixing tape partially exposed. Distal flange slid out.
S-5	13	20	S.	N.			
S-7	13	12	E.	D.			
S-8	8	123	S.	D.		23	Fixing tape well embeded.
S-13	11	260	S.	N.→D.	3.6	7	Giant stone was produced. Pr. mirabilis, Str. faecalis
S-14	10	7	B. R.	D.		75	Tube obstructed with blood coagula.
S-15	7	33	S.	N.		0	
S-16	7	13	?	D.		2	Fixing tape completely exposed.
S-17	8	45	S.	D.	1.0	0	Fixing tape completely exposed.
S-18	9	6	B. R.	D.		350	Tube obstructed with blood coagula.
S-19	12	10	S.	N.	5.7	0	
S-20	13	23	S.	N.	5.2	12	
S-21	8	42	S.	D.		3	
S-22	10	14	S.	N.	6.9	0	
S-23	12	112	E.	N.			
S-24	16	47	S.	D.	3.0	10	
S-25	12	59	S.	D.	2.7	5	

S: sacrificed I: incontinence N: normal urination
D: dysurination B.R: bladder rupture E: escaped

Table IV Balloon Valve Group.

Dog No.	Weight (kg)	Length of Survival (days)	Cause of Death	State of Urination	Flow Rate (cc/sec)	Residual Urine (cc)	NOTES
B-1	15	71	S.	I.		0	Urinary salts on the balloon.
B-2	13	93	S.	N.→D.	1.2	500	Urinary salts on the balloon. Balloon collapsed. Pr. mirabilis, Str. faecalis
B-3	12	101	S.	N.→D.	0.8	1,500	Valve dislocated into bladder. Balloon collapsed. Stricture at bladder neck.
B-4	8	66	S.	I.		3	Bacillus pyocyaneus
B-5	12	67	S.	N.	4.3	0	Normal urination until the day before sacrifice.
B-6	10	35	E.	N.			
B-7	11	3	B. R.	D.		50	Balloon collapsed
B-8	8	32	S.	N.	5.0	2	Pr. mirabilis, Str. faecalis
S-9	7	16	S.	N.	4.7	0	
B-10	13	45	S.	N.	4.5	0	Proteus mirabilis

S: sacrificed I: incontinence N: normal urination
D: dysurination B.R: bladder rupture E: escaped

reference to the tissue reaction to prosthetic materials.

Bacteriological studies were tried in several cases.

III RESULTS

Results are shown in Table III and IV.

(1) Preliminary Experiments.

Vinyl chloride tubes without valve mechanism were inserted and fixed with the same method as mentioned above (No. T-1 and T-3).

All animals showed incontinence following the operation. These animals began to void at the bladder capacity of 15 or 32 cc and their voiding pressures were not more than 10 cm H_2O.

(2) Cystometry.

Normal cystometry: In normal dogs, the voiding pressure ranged from 36 to 74 (cm H_2O) and the bladder capacity at voiding from 50 to 280 (cc).

Postoperative cystometry (Table V and VI):

Straight valve group (Fig. 6 and 7): Straight valves themselves had the considerable low opening pressures, ranging from 26 to zero (cm H_2O). After insertion of the valves, however, the voiding pressures (viz. their opening pressures in the urethra) increased.

Balloon valve group (Fig. 8): In this group, the voiding pressures were almost the same as the opening pressures of the valves, unless the valves collapsed and failed to restore to their original states. In other words, the voiding pressures were obtained

Table Ⅴ CYSTOMETRY (Straight Valve Group)

Dog No.	PRE-operative		POST-operative	
	Pressure (cm H_2O)	Volume (cc)	Pressure (cm H_2O)	Volume (cc)
T- 1	49	120	7	15
T- 3	62	180	9	32
S- 4	42	195	81.6	300
S- 5	40	210	32.6	210
S- 7	65	180	50	180
S- 8	63	180	73.4	310
S-13	43	260	—	—
S-14	44	220	—	—
S-15	38	80	32.6	35
S-16	40	100	—	—
S-17	62	50	24.5	18
S-18	—	—	—	—
S-19	60	170	—	—
S-20	52	280	—	—
S-21	—	—	—	—
S-22	42	—	26.6	200
S-23	—	—	—	—
S-24	41	150	27	120
S-25	—	—	—	—

Table Ⅵ CYSTOMETRY (Balloon Valve Group)

Dog No.	PRE-operative		POST-operative	
	Pressure (cm H_2O)	Volume (cc)	Pressure (cm H_2O)	Volume (cc)
B- 1	74	80	20	32
B- 2	—	—	—	—
B- 3	—	—	—	—
B- 4	36	100	20	42
B- 5	60	120	14	50
B- 6	42	130	28	150
B- 7	56	130	—	—
B- 8	60	170	—	—
B- 9	50	85	36	120
B-10	54	240	—	—

Fig. 6 Cystometrogram of No. S-4.

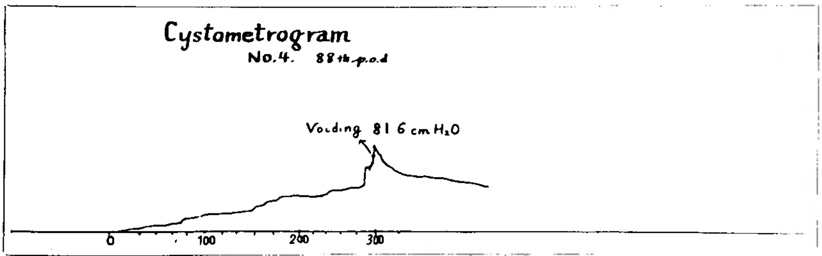
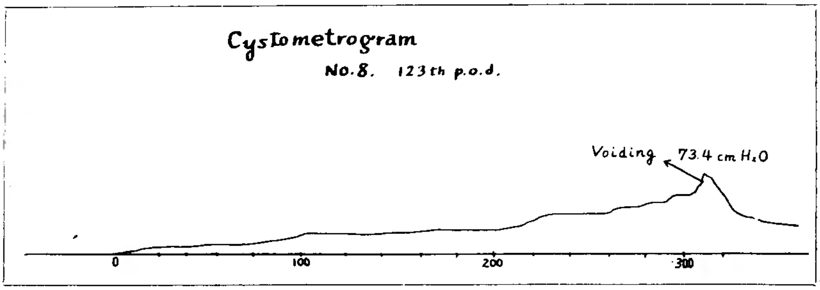


Fig. 7 Cystometrogram of No. S-8.



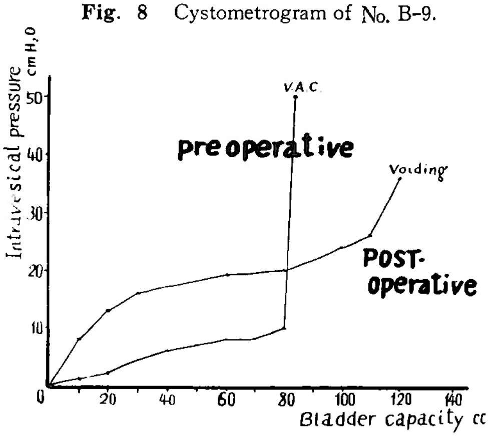
at the expected range in most of the cases.

(3) Observation of Urination.

For evaluation of results, the state of urination was divided into three groups: incontinence, normal urination and dysurination (Table III and IV).

In the straight valve group, animals had a tendency of dysurination. On the other hand, in the balloon valve group, the state of urination was generally better than the former group, except for some cases which fell into dysurition or incontinence. No. B-5, for example, voided in the nearly normal state and its uroflogram showed 4.3 cc/sec, but on the following day, her genitalia and hind legs became wet and fell into incontinence. This was due to collapse of the balloon.

Fig. 8 Cystometrogram of No. B-9.

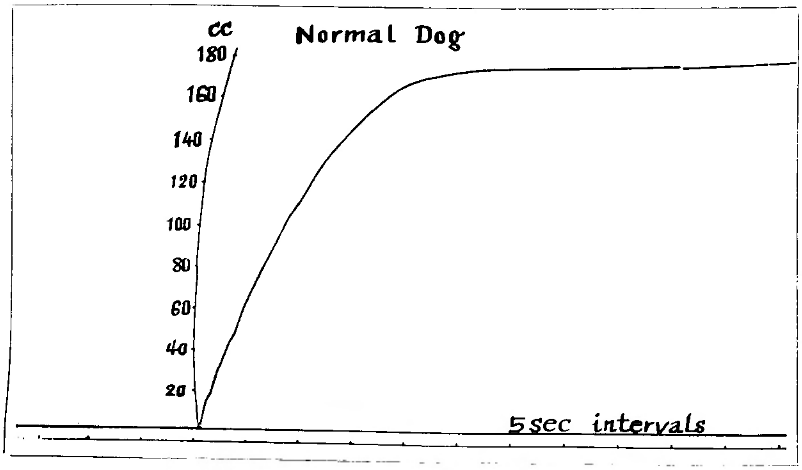


In both groups, if the valve was dislocated into the bladder, the state of urination was improved, but, after a while, serious dysurination developed.

(4) Analysis of Urination by means of Uroflometer.

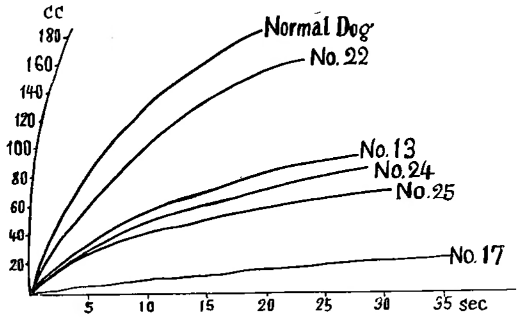
After Besacholine injection, urinary flow rate of normal dog was 8 cc/sec (Fig. 9).

Fig. 9 Uroflogram of the normal dog.



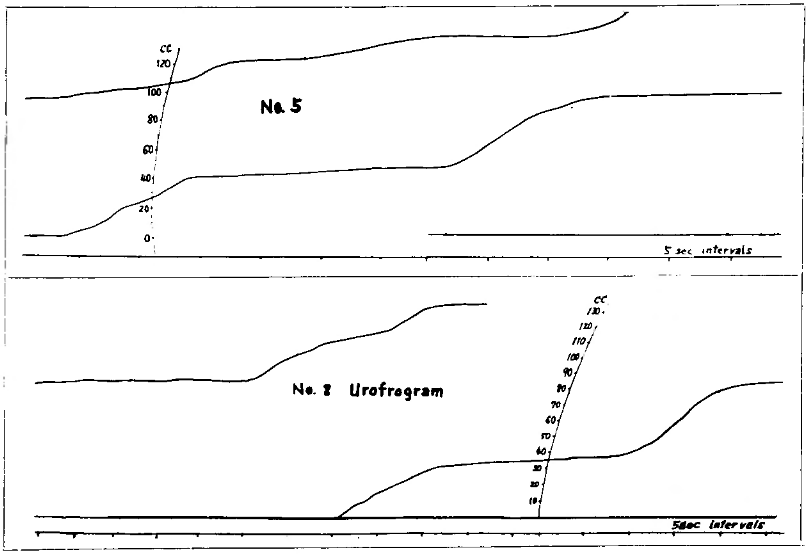
Straight valve group: Urinary flow rates generally decreased after insertion of the valves, although there were cases in which urinary flow rates remained approximately normal. Prolongation of the voiding time was a characteristic feature in this group (Fig. 10). And there was a decreasing tendency in the urinary flow rate, as the day passed after the operation. Urinary flow rates were related to the opening pressures of the valves and to the positions of the slit in the urethra.

Fig. 10 Uroflograms of the straight valve group.



Balloon valve group: Several cases showed nearly normal uroflogram, but generally dysurination was observed. Uroflograms of dysurination showed the stepped elevation of the curves, suggesting that urine was fractionally excreted, so dysurination was due to the less volume of urine per void (Fig. 11). In animals of incontinence group, uroflograms were flat even after Besacholine injection.

Fig. 11 Uroflograms of the balloon valve group.



Above No. B-5, Below No. B-8.

(5) Residual Urine.

Straight valve group: Residual urine volume ranged from zero to 350 (cc). But in most of cases, this volume was 10 cc or so.

Balloon valve group: Residual urine was not at all obtained except for three cases (No. B-2, 3 and 7). No. B-2 and 3 were the cases of which the bladder necks were obstructed following dislocation of the valves. And in No. B-7, the balloon was collapsed and the slit was obstructed.

By the culture of residual urine, as shown in Table III and IV, Proteus mirabilis, Streptococcus faecalis were present in several cases and Bacillus pyocyaneus in one case.

(6) Quantitative Measurement of Serum Urea-Nitrogen (Table VII and VIII).

There were no cases in which these values became extremely high postoperatively, except for several cases (No. S-14, B-3 and 9).

There was not any close relationship between the state of urination and the value of serum urea-nitrogen, and any significant difference of this value between the straight valve group and the balloon valve group.

Table VII SERUM UREA-NITROGEN (Straight Valve Group)

	PRE-operative	POST-operative
S-8	10.5mg/dl	19.2mg/dl
S-13	9.7	9.6
S-14	—	27.4
S-15	7.8	10.5
S-16	13.2	—
S-17	9.2	13.3
S-18	7.5	—
S-19	7.3	7.9
S-20	6.4	4.7
S-21	10.2	6.7
S-22	9.5	11.2
S-23	8.6	—
S-24	7.6	9.0
S-25	9.3	12.2

Table VIII SERUM UREA-NITROGEN (Balloon Valve Group)

	PRE-operative	POST-operative
B-1	7.3mg/dl	11.0mg/dl
B-2	7.5	8.3
B-3	9.2	19.5
B-4	5.5	10.0
B-5	5.2	10.0
B-6	5.6	9.8
B-7	8.8	—
B-8	9.0	9.6
B-9	7.5	25.4
B-10	6.6	—

(7) Patho-Histological Findings.

(A) Pathological Findings (Fig. 12 to 20).

Bladder: In some cases, the bladder walls were dilated and became about twice as thick as they were. And their inner faces were flattened and whitish in color.

Ureter: There were a few cases in which ureters were moderately dilated, but in most of the cases, they were nearly normal.

Kidney: No characteristic findings were observed. In one case, cicatricial contraction probably due to infection was present (Fig. 14).

Bladder neck: As the valves were fixed in this site with a fixing tape, various findings were obtained. In one case, the fixing tape was well embeded for four months (Fig. 13), but in some cases, these tapes were exposed partially or completely in the urethra. And there was a case in which this tape was already exposed as early as the 13th day after the operation.

Urinary stone or salts: In a case, giant vesical stones were produced on the top of the vinyl chloride tube (Fig. 14). Urinary salts were precipitated on the silicone tube (for industrial use) (Fig 12) or on the rubber balloon without silicone coating (Fig. 18). But on the silicone valves made of Phycon tube and on the rubber balloon with silicone coating, urinary calculi were not produced.

Qualitative analysis proved these calculi to be phosphatic in nature.

(B) Histological Findings.

Kidney (Fig. 21 to 24) : There were no apparent changes in kidneys.

Cortex : Lymphocytic infiltration was seen in a few cases (No. S-4, 8, 17 and B-3), and renal tubules were slightly degenerated but there were no intratubular urinary casts. Dilatation of renal tubules was not seen. Glomeruli were nearly normal.

Marrow : In No. S-3, 17, B-3 and 8, lymphocytes were slightly infiltrated, probably due to chronic pyelitis. Renal calyces of No. S-3 was slightly dilated. In one case (No. S-15), microscopic renal calculus was seen.

Bladder (Fig. 25 to 28) : Uroepithel of the bladder was generally thin, lacking partially. The muscular layer became thick, and proliferation of the connective tissue and also new growth of the blood vessels was seen in the submucous layer.

Bladder neck :

First Month.

Fixing tape Tetron (Fig. 29) : Lymphocytes, histiocytes and some leukocytes (chiefly eosinophilic leukocytes) were infiltrated around the tape. Near the foreign body, giant cells were seen. In some cases, there was leukocytic infiltration.

Fixing tape Polyvinyl formal sponge (Fig. 30) : Infiltration of lymphocytes, histiocytes was more remarkable in the sponge *per se* in contrast to its surrounding tissue, rendering it distinctly demarcated. In some cases, leukocytes were infiltrated in the submucous layer, probably due to local infection.

Second Month.

Fixing tape Tetron : In the submucous layer, infiltration of lymphocytes was mild.

Third Month.

Fixing tape Tetron (Fig. 31) : Tissue reaction around the tape subsided in some degree, but in the Tetron fabrics, lymphocytes, histiocytes and leukocytes were remarkable.

Fixing tape Polyvinyl formal sponge (Fig. 32) : There was no tissue reaction around the sponge. On the other hand, in the sponge, lymphocytes, histiocytes and giant cells were noted.

Fourth Month.

Fixing tape Tetron (Fig. 33) : In the submucous layer, especially near the fabrics, proliferation of the connective tissue was markedly seen, and lymphocytes were decreased.

In cases without infection, leukocytes, afterwards, lymphocytes and histiocytes infiltrated, later the foreign body was seemed to be gradually absorbed and replaced with the connective tissue.

Tissue reaction to the Polyvinyl formal sponge was characteristic in such a point that cell infiltration was scarcely seen around the sponge, but remarkable in it. On the other hand, intensive cell infiltration was noted around the Tetron fabrics. Tissue reaction to this fabrics was slightly intense than surgical threads, and the Polyvinyl formal sponge seemed to be more easily absorbed and organized than the Tetron fabrics.

Fall-out phenomenon of the fixing tape was referred to infection and tissue reaction. If infiltration of leukocytes was intensive and microabscess formation took place in the submucous layer, the uroepithel and submucous layer of the bladder neck were easily destroyed with pressure necrosis and the fixing tape was exposed in the urethral lumen, resulting in progressive infection into the deep layers. Later, the uroepithel regenerated and covered around the tape (Fig. 34). Such regeneration seemed to be originated from the anti-foreign body action for the repair of injured tissues

(8) **Thick Wall Balloon Valve.**

Next, the thick wall balloon valve was prepared, lest the balloon should fall into permanent collapse with the intravesical pressure or with the bladder contraction at voiding.

Opening pressures of the valves were 92, 103 and 125 cm H O respectively.

Voiding did not occur by the mere infusion of water into the bladder through the distal end of the tube. At that time, the vesical capacity was at least 100 cc and forcible voiding was initiated only by the manual pressure on the abdominal wall (Fig 35 and 36).

Fig. 35 Urinary excretion of No. B-11. (Thick wall balloon valve)

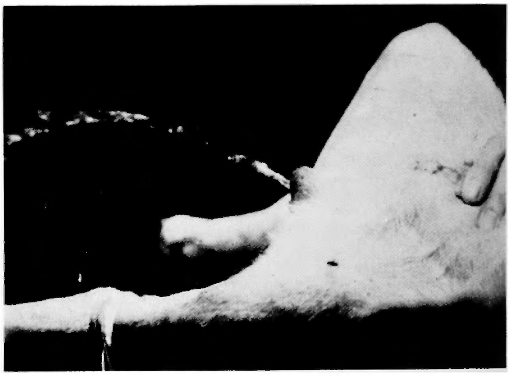


Fig. 36 Urinary excretion of No. B-15. (Thick wall balloon valve)

Postoperative observation on these animals was not performed because they could not void by themselves.

(9) **Application to the Clinical Case.**

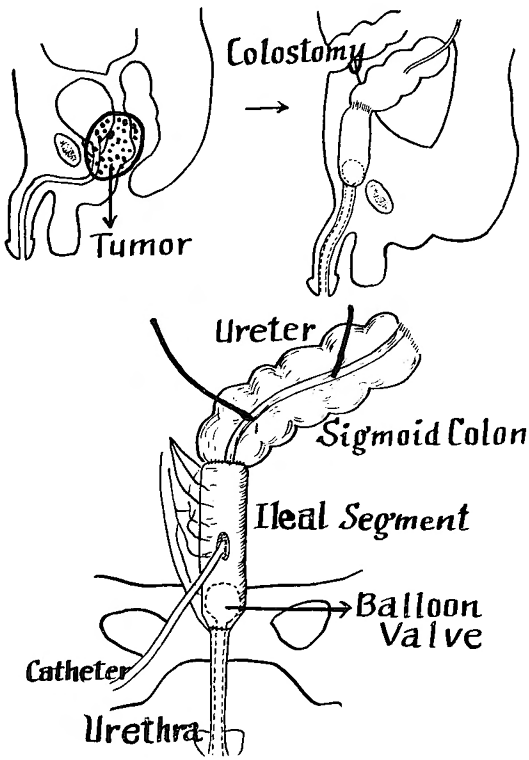
A 52-year-old man, suffering from vesical cancer and its rectal invasion, was operated on June 28, 1961. As a primary procedure, the rectum, bladder and prostate were resected and the both ureters were implanted to the sigmoid colon, and a colostomy was performed. On October 18, 1961, the sigmoid with ureters was separated from the gastrointestinal tract and substituted for the bladder. Next, the ileal segment with the mesentery was interposed between the new bladder and the membranous urethra (that is, KIMURA's antepubic vesico-ileal neourethrostomy). Then, the thick balloon valve made from silicone was placed at the ileo-urethral junction, and another catheter was inserted to the interposed ileum, as shown in Fig 37.

After the operation, the patient was uneventful.

Evaluation of the Artificial Valve: The opening and closing pressure of this valve was 132 and 42 cm H_2O respectively. Urine was excreted through the ileal catheter and this valve. If the ileal catheter was stopped, voiding did not occur, but urine spurted by the manual pressure on the abdominal wall and also with peristaltic movement of the sigmoid colon and ileum. For about a week after the operation, this valve functioned successfully, but later the balloon became collapsed and the slit at its top duplicated due to contracture of the ileum and to skin tension, and finally this valve had to be drawn out.

The ileal catheter was often obstructed with urinary salts and mucus from the new bladder, but this valve was free from urinary salts, through which the bladder was easily irrigated.

Fig. 37



IV DISCUSSION

Many reports have been made on the anatomical reconstruction of the urinary tract but few on the functional restoration of the vesical sphincter. These are summ-urized as follows.

(A) **Restoration of the Vesical Sphincter.**

(1) Reinforcement of the urethral resistence.

Numerous techniques, termed as "sling operation", have been reported. At first, transplantation of voluntary muscles was recommended to relieve urinary incontinence. The results were often disappointing, for the muscles could not be transplanted without complete destruction of their nerve and blood supply. Then, the muscle fascias or the alloy stainless steel wire were used instead of muscle transplants. These methods have been favorably applied to stress incontinence, but do not touch on the problem of the urethral reconstruction.

(2) Application of the intestinal segment.

The intestinal segment has often been utilized for substitutes of the urinary tracts (the ureter, bladder and urethra). Especially expecting the Bauchin's valve to perform sphincterlike function, Gilchrist, Wenger, Eiseman and others separated the cecum and right colon and terminal ileum *en bloc*, and applied the latter for the substitute of the urethra and the former for the bladder. Smith and Hinman interposed the intussuscepted ileum between the abdominal wall and bladder, and confirmed that this ileal segment was able to retain urine. In these methods, drawbacks were that voiding should be made from the unnatural orifice.

Kimura, Harada and Tatsumi, in the author's laboratory, reported a method of "antepubic vesico-ileal neourethrostomy", that is, the isolated ileal segment with its mesentery was interposed antepubically between the bladder and membranous urethra. And with additional application of the belt on the pubic bone, urinary continence was successfully obtained.

FUKUYAMA applied experimentally the intussuscepted ileal valve interposing between the anterior urethra and ureters or bladder.

These two operations were the methods in which urination was from the normal orifice, and associated with reconstruction of the urethra as well as with urinary control.

(3) Flap method.

This method was reported by YOUNG, MILLS and BURNES. "Flap tube", made of the bladder wall, was utilized as substitutes of the ureter and urethra. According to the LAPIDES' study, this tube has the same function as the internal sphincter, so it is able to control urination, if this tube is long enough.

Later, TSUJI, KURODA and ISHIDA reported that this flap tube could be made of the bladder wall secondarily utilizing the regeneration ability of the uroepithel.

(4) Artificial sphincter apparatus.

This is the method to reconstruct the vesical sphincter with an artificial valve.

FOLEY reported on a certain device of the artificial sphincter. This was deviced to compress the urethra separated from the surrounding tissues.

SWENSON, in 1949, interposed a prosthetic valve between the abdominal wall and bladder, and urination was controled. Later, in 1956, he constructed a doughnut type rubber bag which compressed the perineal urethra with the inflated bag.

These artificial sphincters or valves were applied clinically.

(B) Reconstruction of Sphincters and Valves in other Organs.

(1) Intussusception method.

This is the method to reconstruct the sphincter or valve with invagination of a portion of the hollow viscus wall.

PEARL applied this method to jejunostomy to prevent constant leakage of jejunal contents. EISEMAN et al. applied this method to the inferior vena cava of experimental animals. HARADA also applied it to the major saphenus vein with varicose vein and reconstructed the venous valve. SILEN et al. applied it to the aorta suffering from aortic regurgitation.

(2) Transplantation of the Bauchin's valve.

The terminal ileum, cecum and ascending colon involving the Bauchin's valve was interposed between the esophagus and cardia of the stomach to prevent regurgitation esophagitis. This method was applied by LEE, HUNNICOTT and others.

(3) Nipple method.

This technique consists of forming a nipple composed of a full thickness flap of the large hollow viscus wall, wrapped around and sutured to the narrow hollow viscus. Such an anastomosis will prevent regurgitation, since a stoma of the narrow hollow viscus is compressed and closed, as the large hollow viscus becomes distended.

Utilizing this method, MATHISEN prevented ureteral reflux at uretero-colonic anastomosis. DILLARD applied this method to regurgitation esophagitis.

(4) Slit valve.

The major component of this valve is a plastic tube closed at one end and fitted with a small slit at its lateral border. Then, this slit plays valve-like function to control the pressure on the opposite open end of this tube.

PUDENZ applied this valve to the patients suffering from hydrocephalus to shunt cerebrospinal fluid from the brain ventricle to the auricle of the heart.

KOHLER inserted similar valves, made of silicone, and transplanted permanently at the site of the vesicoureteral junction to prevent ureteral reflux.

(5) Miscellaneous.

Numerous valves have been designed and studied in the field of cardiovascular surgery, as reported in "Prosthetic Valves for Cardiac Surgery", edited by MERENDINO.

As mentioned above, there have been two channels for restoration of the urinary vesical sphincter: one is the way to utilize biologic structures and the other is to utilize non-biologic prostheses. Almost all kinds of biologic structures had been used in the past for this purpose, resulting in complete failures or in very restricted successes. So it seems to be difficult to expect functional restoration with these biologic structures.

For the prosthetic valve, it is very important to debate both the materials and functions of the valve.

Prosthetic materials had been either considered to be dangerous or discarded as "foreign bodies" by surgeons. But the great strides have been made in the field of highpolymer chemistry; which has given and also in future will give us much more excellent materials.

These materials should be inert in the tissue, stable physically, of easy workability and non-carcinogenic. At present, silicone is the most excellent material for these prostheses. But almost all of failures in this study seemed to be referred to applied prostheses.

(1) Dislocation of valves into the bladder: In some cases, sloughing occured at the bladder neck where valves were fixed, and fixing tapes fell out into the urethra and then valves slid into the bladder, contrary to the author's expectation that these tapes should become more tightly fixed with inward tissue proliferation. Such fixation method seems to be unsuitable.

(2) Stone formation: As these prostheses came always in contact with urine, reaction of urine to them comes into question. VERMEUREN et al. reported that various kinds of foreign bodies were inserted into the bladder of rats and urinary stones were produced, but polythene failed to become nuclei for stone formation. This fact is promising in the future development of the suitable plastic materials.

Hydrodynamic Functions of these Valves.

(1) Straight valve.

When the intravesical pressure becomes high and reaches a certain level, the slit is open and then voiding starts. The opening pressure of this valve correlates reversively with the length of the slit (Fig. 38), on the other hand, the flow capacity has a correlative relationship with the length of this slit.

(2) Balloon valve.

(i) Thin wall balloon valve: When the intravesical pressure becomes high over the certain level, the balloon is compressed and deformed, then the slit at the top of the balloon is forced to be open, and intravesical contents flow out. As urine is excreted,

Fig. 38 Relation between the opening pressure of the straight valve and the length of the slit.

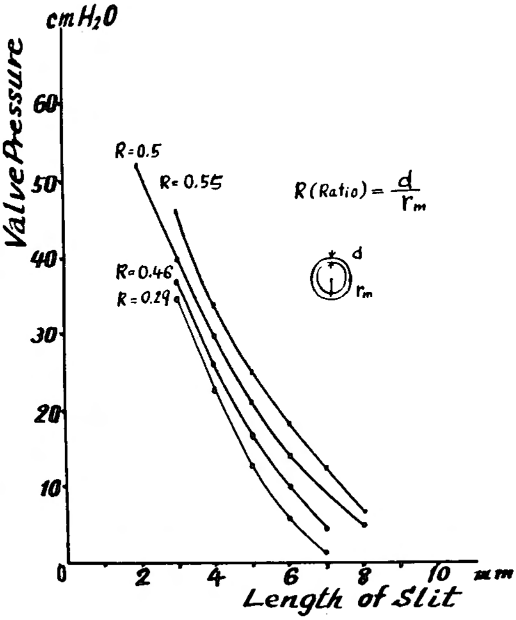


Fig. 39 Relation between the opening pressure of the thin wall balloon valve and the length of the slit.

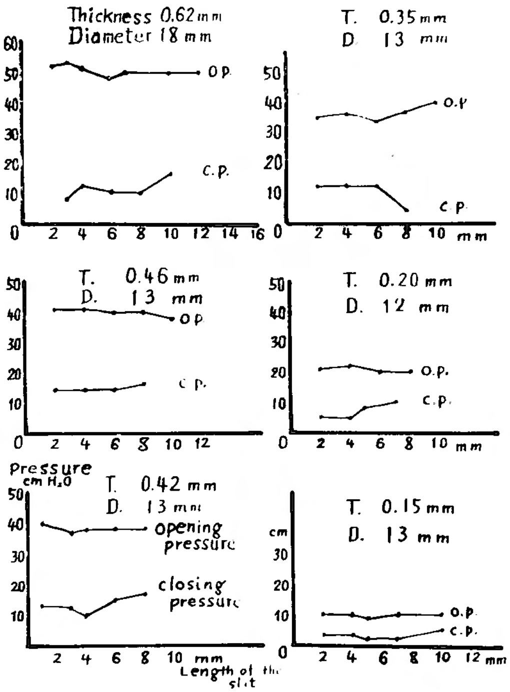
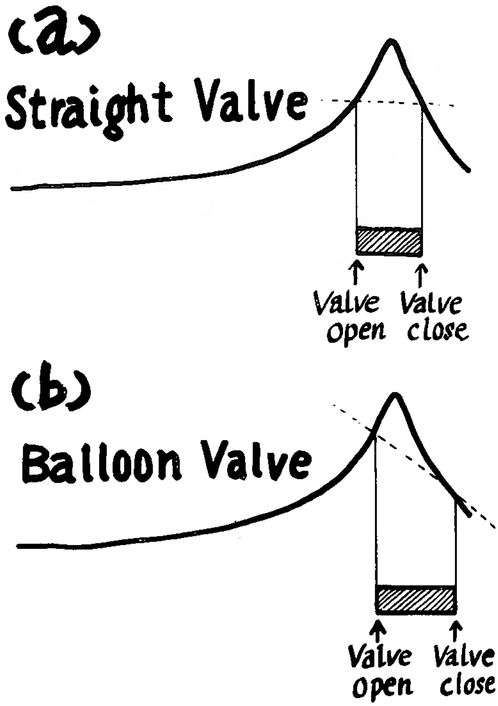


Fig. 40 Cystograms and function of the two valves. (Schematic diagrams)



the intravesical pressure becomes low to a certain level and the balloon restores automatically to its original state, and then voiding stops. The opening pressure changes with the thickness of this balloon and not with the length of the slit (Fig. 39). On the other hand, the flow capacity is determined with the length of the slit and probably with the diameter of this balloon.

(ii) Thick wall balloon valve: This valve has the same appearance as the thin wall balloon valve, as mentioned before. As the wall of this balloon is thicker, its opening pressure is considerably high not to open at the pressure of the normal vesical contraction. When urine accumulates in the bladder, the slit can be opened by the manual pressure on the abdominal wall, and then vesical contents begin to spurt.

Comparison of these Valves.

(1) Faults of the straight valve.

(i) This valve is open and close at the same level of the pressure, so animals may be in danger to result in overflow incontinence (Fig. 40, a).

(ii) It is difficult to construct the slit valve, having a certain level of the voiding pressure, because of the lateral pressure of the urethral wall.

(iii) Inability to bladder irrigation.

(2) Faults of the thin wall balloon valve.

(i) The balloon tube may be the cause of infection, for the distal end of this tube has to be open at the external urethral orifice due to restoration of the balloon.

(ii) Disorder of urination may occur, because the thin wall balloon valve was occasionally collapsed with the vesical contraction and could not restore to its original state.

(3) Merits of the balloon valve.

(i) This balloon valve seems to have similar mechanism to that of the normal vesical sphincter, because this valve has a wide range between the opening and closing pressure (Fig. 40, b).

(ii) Easy accessibility to bladder irrigation.

(iii) Besides, the thick wall valve was improved to be controled by the manual pressure on the abdominal wall.

V SUMMURY AND CONCLUSION

Up to the present time, application of the plastic materials has not been tried for the functional restoration of the injured urinary sphincter. The author devised several kinds of the prosthetic valves for this purpose : the straight valves and the balloon valves, which were applied to animals and also to the clinical case.

Results were summurized as follows.

(1) Comparing the two kinds of valves, excellent results were obtained with the balloon valves rather than with the straight valves, and the former seemed to have functionally closer resemblance than the latter to the normal vesical sphincter.

(2) After insertion of the valves, nearly normal urination was observed in 8 out of 17 cases of the straight valve group, and in 7 out of 10 cases of the balloon valve group. The rest showed, to various extent, disorder of urination.

(3) The causes of failures were referred to collapse of the balloon or dislocation of the valve.

(4) There were some cases in which urinary stones were produced. Stone formation was affected with the kind of the prosthetic materials. Phycon (silicone rubber for medical use) had the least tendency of stone formation.

(5) In the clinical case, incontinence was prevented with the thick wall balloon valve. And it was desirable that the balloon wall was thick enough not to be compressed and deformed with the visceral (ileal or vesical) wall, and with peristalsis.

(6) In this study, the author tried to accomplish the valves which could be embeded permanently in the tissue and reacted automatically with the intravesical pressure, and

the author proved that the balloon valve, especially the thick wall balloon valve, was applicable clinically with good results.

It was most desirable that these valves could be inserted or drawn out easily with improvement of the fixation method. And there seemed to be another solution of the problem of the urinary control by means of some urethral compressors such as the KIMURA's antepubic belt or the "pneumatic sphincter" by FOLEY and SWENSON.

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REFERENCES

1) Akiyama, T. : Medicine and synthetic resins (in Japanese). Geka no ryōiki, **4**, 777, 1956., **5**, 177, 407, 940, 1001 & 1175, 1957., **6**, 1, 211, 337, 416 & 481, 1958.
2) Aldridge, A. H. . Transplantation of fascia for relief of urinary stress incontinence. Am. J. Obst. & Gynec., **44**, 398, 1942.
3) Barnes, R. W. and Farley, S. E. : Reconstruction of lower segment of ureter with tube made from bladder flap. Preliminary report. J. Urol., **59**, 466, 1948.
4) Basso, D. E. : The efficacy and applicability of an intussuscepted conical valve in preventing regurgitation and leakage of intestinal contents. Ann. Surg., **133**, 477, 1951.
5) Bricker, E. M. and Eiseman, B. : Bladder reconstruction from cecum and ascending colon following resection of pelvic viscera. Ann. Surg., **132**, 77, 1950.
6) Brown, H. P. and Harrison, J. H. : The efficacy of plastic ureteral and urethral catheters for constant drainage. J. Urol., **66**, 85, 1951.
7) Brown, J. B. et al. : Polyvinyl and silicone compounds as subcutaneous prosthesis. A. M. A. Arch. Surg., **68**, 744, 1951.
8) Cooney, C. J. and Horton, G. R. : An operation for cure of incontinence in the male. J. Urol., **66**, 586, 1951.
9) Davids, A. M. and Lesnick, G. L. : Experimental reconstruction of ureters by substitution of small bowel segment. Ann. Surg., **137**, 389, 1954.
10) DeNicola, R. R. : Permanent artificial (silicone) urethra. J. Urol., **63**, 168, 1950.
11) Dillard, D. H. et al. : The surgical construction of an esophageal valve to replace the "cardiac sphincter". An experimental study. Surgical Forum, **5**, 306, 1954.
12) Drake, W. M. Jr. : The uroflometer : An aid to study of the lower urinary tract. J. Urol., **59**, 650, 1948.
13) Eiseman, B. and Malette, W. : An operative technique for the construction of venous valves. Surg. Gynec. & Obst., **97**, 731, 1953.
14) Elliot, J. S. : Postoperative urinary incontinence, a revised concept of the external sphincter. J. Urol., **71**, 49, 1954.
15) Ferris, D. O. and Grindlay, J. H. : Use of polythene and polyvinyl tubing in ureterostomy, nephrostomy and cystostomy. Proc. Staff Meet. Mayo Clinic, **23**, 385, 1948.
16) Figueroa-Colon, J. et al. : The experimental repair of urethral defects. Surgery, **38**, 1043, 1955.
17) Foley, F. E. B. : An artificial sphincter : A new device and operation for control of enuresis and urinary incontinence. J. Urol., **58**, 250, 1947.
18) Folet, J. : Réfection de l'urethre par tube de polyethène. J. d'Urol. (Paris), **59**, 675, 1950.
19) Fukuyama, K. : Experimental study of the ileal bladder with an intussuscepted ileal valve (in Japanese). J. Osaka City Med. C., 8, 957, 1959.

20) Gale, J. W. et al. : Plastic sponge prosthesis following resection in pulmonary tuberculosis. J. Thorac. Surg., **24**, 587, 1952.
21) Gilchrist, R. K. et al. : Construction of a substitute bladder and urethra. Surg. Gynec. & Obst., **90**, 752, 1950.
22) Harada, N. et al. : Construction of venous valve as a treatment of varicose veins. Arch. Jap. Chir., **25**, 29, 1956.
23) Harada, N. et al. : Construction of a urothelial urinary conduit by a free graft of bladder mucosa to the peritoneum. Plast. & Reconstr. Surg., 26: 57, 1960.
24) Hardin, C. A. : Experimental repair of ureters by polyethylene tubing and ureteral and vessel grafts. A. M. A. Arch. Surg., **68**, 57, 1954.
25) Harrison, J. H. et al. : A comparison of the tissue reactions to plastic materials. A. M. A. Arch. Surg., **74**, 139, 1957.
26) Herger, C. C. et al. : The value of the stone dissolving agent, solution G, in the treatment of alkaline incrustations of bladder lesions. Surg. Gynec. & Obst., **77**, 634, 1943.
27) Johnson, T. H. : Further experiencences with a new operation for urinary diversion. J. Urol., **76**, 380, 1956.
28) Kimura, C. et al. : Antepubic vesico-ileal neourethrostomy. J. Urol., **77**, 227, 1957.
29) Kodama, M. : Experimental and clinical studies on the ureteral transplantation using chiefly arterial grafts preserved in alcohol (in Japanese). Jap. J. Surg. Soc., **56**, 1339, 1956.
30) Kohler, F. P. and Murphy, J. J. : A mechanical ureteral valve. Surg. Gynec. & Obst., **109**, 703, 1959.
31) Lapides, J. : Observation on normal and abnormal bladder physiology. J. Urol., **70**, 74, 1953.
32) Lary, B. G. and Scheibe, J. R. : The effect of rubber tubing on the healing of common duct anastomosis. Surgery, **32**, 789, 1952.
33) Lord, J. W. Jr. and Eckel, J. H. : The use of vitallium tubes in the urinary tract of the dog. J. Urol., **48**, 412, 1942.
34) Lord, J. W. Jr. et al. : On bridging a gap in the ureter by means of a free fascial transplant over a straight vitallium tubes : An experimental study. J. Urol., **49**, 249, 1943.
35) Lowsley, O. S. and Johnson, T. H. : A new operation for creation of an artificial bladder with voluntary control of urine and feces. J. Urol., **73**, 83, 1955.
36) Lubash, S. : Experiences with tantalum tubes in the reimplantation of the ureters into the sigmoid in dogs and humans. J. Urol., **57**, 1010, 1947.
37) Mackler, S. A. and Mayer, R. M. : Palliation of esophageal obstruction due to carcinoma with a permanent intraluminal tube. J. Thorac.Surg., **28**, 431, 1954.
38) Marshall, V. F. et al. : Correction of stress incontinence by simple vesico-urethral suspension. Surg. Gynec. & Obst., **88**, 509, 1949.
39) Martin, L. S. J. et al. : Uroepithelial lined small bowel as a ureteral substitute. Surg. Gynec. & Obst., **108**, 439, 1959.
40) Maurer, J. E. and Lich, R. Jr. : Surgical correction of female stress incontinence. J. Urol., **67**, 644, 1952.
41) McGregor, R. R. : Silicones in medicine and surgery. Dow Corning Corporation, Midland, Michigan. 1957.
42) McLean, D. W. and Fais, O. G. : The use of segments of small intestine as ureters. J. Urol., **68**, 190, 1952.
43) Merendino, K. A. : Prosthetic valves for cardiac surgery. Charles C Thomas Publisher, Springfield, Illinois. 1961.
44) Ockerblad, N. F. : Reimplantation of the ureter into the bladder by a flap method. J. Urol., **57**, 845, 1947.
45) Okuda, Y. : Cytological observation of the inflammatory reactions by phase contrast microscopy. (II) Inflammatory reaction caused with polyvinyl formal and cellulose (in Japanese). Rep. Tuberc. Res. Inst., Kyoto Univ., **4**, 103, 1955.
46) Pearl, J. I. : Intussuscepted conical valve formation in jejunostomies. Surgery, **25**, 297, 1947.
47) Prien, E. L. : Studies in urolithiasis : III. Physicochemical principles in stone formation and prevention. J. Urol., **73**, 627, 1955.
48) Pudenz, R. H. et al. : Ventriculo-auriculostomy. A technique for shunting cerebrospinal fluid into

the right auricle. J. Neurosurg., **14**, 171, 1957.
49) Pyrah, L. N. : Some uses of the ileum in urology. Brit. Med. J., No. **4959**, 135, 1956.
50) Rosenberg, M. L. and Dahlen, G. A. : Autogenous vein grafts and venous valves in ureteral surgery: An experimental study. J. Urol., **70**, 434, 1953.
51) Ruch, T. C. and Fulton, J. F. : Medical physiology and biophysics. 18th Ed. W. B. Saunders Co. Philadelphia & London. 1960.
52) Schel, A. M. et al. : Polyethylene as a partial ureteral prosthesis in dogs. J. Urol., **73**, 987, 1955.
53) Schinagel, G. : Correction of stress incontinence in the female. J. Urol., **64**, 573, 1950.
54) Shiraha, Y. et al. : An operative technique of ileourethrostomy after total cystectomy (in Japanese). Operation, **11**, 16, 1957.
55) Silen, W. et al. : The experimental production of a competent aortic valve. Surgery, **40**, 78, 1956.
56) Smith, G. I. and Hinman, F. Jr. : The intussuscepted ileal cystostomy. J. Urol., **73**, 261, 1955.
57) Strauss, A. A. : An artificial ureter made from the abdominal wall. Surg. Gynec. & Obst., **18**, 78, 1914.
58) Strong, G. H. and Van Buskirk, K. E. : An operation for the cure of total urinary incontinence in the male : Report of one case. J. Urol., **66**, 234, 1951.
59) Swenson, O. et al. : A method for controlling urinary incontinence. Surgery, **26**, 405, 1949.
60) Swenson, O. et al. : Treatment of cord bladder incontinence in children. Ann.Surg., **144**, 421, 1956.
61) Taylor, J. N. and Jasper, W. S. : Experimental ureteroneocystostomy by Mathisen technique. J. Urol., **77**, 709, 1957.
62) Tsuji, I. et al. : A new method for the reconstruction of the urinary tract : Bladder flap tube. J. Urol., **81**, 282, 1959.
63) Tulloch, W. S. : Restoration of the continuity of the ureter by means of polyethene tubing. Brit. J. Urol., **24**, 42, 1952.
64) Uhle, C. A. W. and Bradley, R. H. Jr. : The use of rectus fascia and fascia lata in the sling operation for urinary incontinence in the male. J. Urol., **80**, 132, 1958.
65) Ulm, A. H. and Lo, M. : Total bilateral polyvinyl ureteral substitutes in the dog. Surgery, **45**, 313, 1959.
66) Vergés-Flaqué, A. : Flaqué-Lowsley operation for urinary incontinence; Preliminary report. J. Urol., **65**, 427, 1951.
67) Vermeulen, C. W. et al. : Experimental urolithiasis. I. Development of calculi upon foreign bodies surgically introduced into bladders of rats. J. Urol., **64**, 541, 1950.
68) Vermeulen, C. W. et al. : Experimental urolithiasis. III. Prevention and dissolution of calculi by alteration of urinary pH. J. Urol., **66**, 1, 1951.
69) Watkins, D. H. et al. : A method of preventing peptic esophagitis following esophagogastrostomy. J. Thorac. Surg., **28**, 367, 1954.
70) Wenger, D. S. : Substitute bladder after pelvic evisceration for treatment of radiation necrosis. Ann. Surg., **136**, 330, 1952.
71) Young, B. W. and Mills, R. L. : Artificial urethra constructed from a bladder flap : Preliminary report. Plast. & Reconstr. Surg., **12**, 279, 1953.
72) Young, B. W. et al. : Artificial urinary sphincter. Surg. Gynec. & Obst., **113**, 62, 1961.
73) Dow Corning Silicone Notes : Silastic RTV 501. July 1960.
Silastic RTV 731. June 1961.
74) Silicone technical news, provided by A. R. Brown McFarlane & Co., Ltd. Fuji Polymer Industr. Co., Ltd. August 1960.

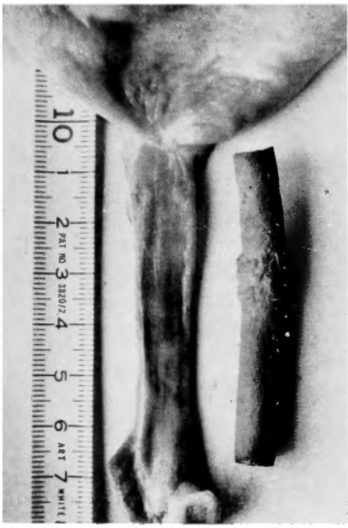
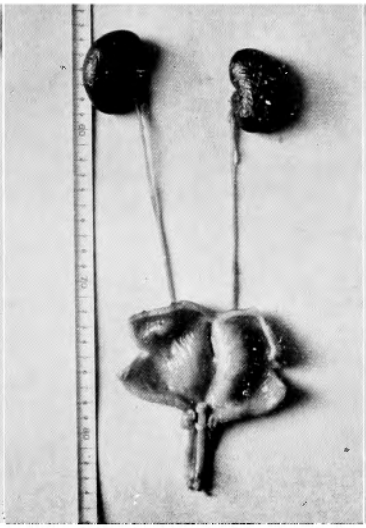


Fig. 12



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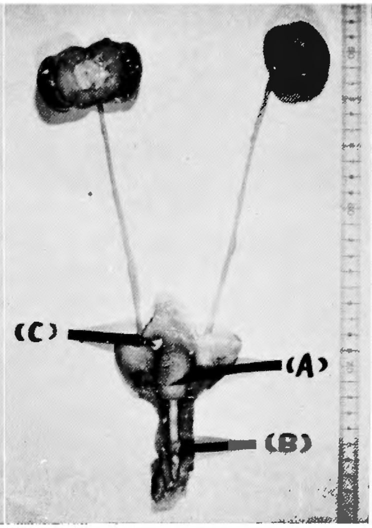

Fig. 14

Fig. 12 No. T-3 Cicatricial contracture at the bladder neck. Urinary salts on the tube. Silicone tube. (338 days)
Fig. 13 No. S-8 Vesical inner face was flattened. Fixing tape well embeded. Straight type valve. (123 days)
Fig. 14 No. S-13 Giant vesical stone on the top of the valve (A) and its daughter calculi (B and C). Kidneys contracted. Straight type valve. (260 days)

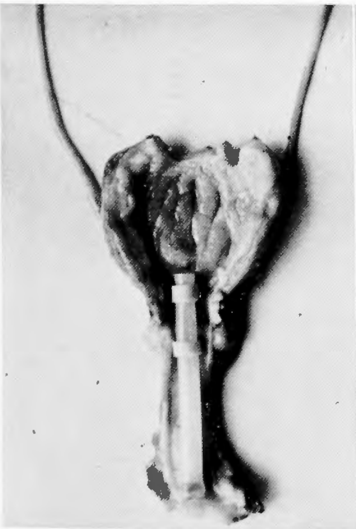

Fig. 15

Fig. 16

Fig. 17

Fig. 15 No. S-20 Straight type valve. (23 days)
Fig. 16 No. S-22 Funnel type valve. (14 days)
Fig. 17 No. S-25 Funnel type valve. (59 days)

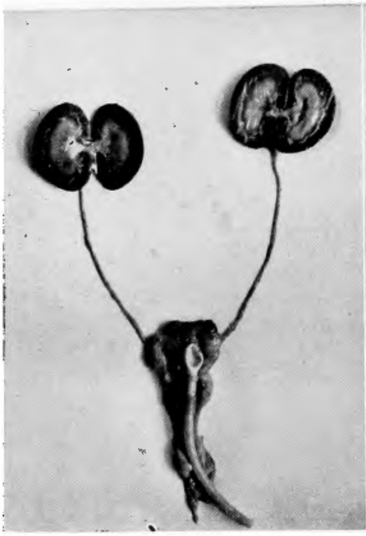

Fig. 18 **Fig. 19** **Fig. 20**

Fig. 18 No. B-2 Balloon was collapsed. Urinary salts precipitatated on the balloon. Thin wall balloon valve. (93 days)

Fig. 19 No. B-3 The valve dislocated in the bladder. Thin wall balloon valve. (101 days)

Fig. 20 No. B-5 Thin wall balloon valve. (67 days)


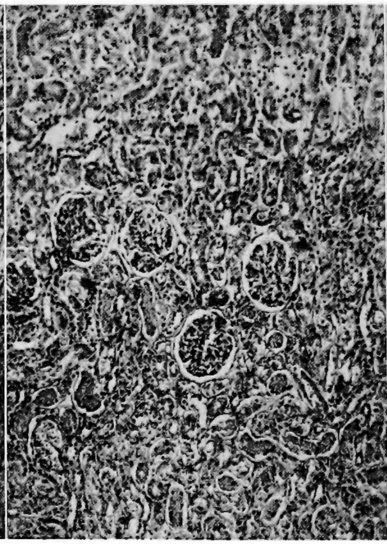
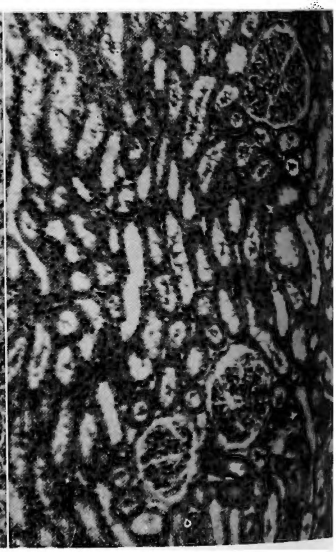

Fig. 21 Kidney No. B-4 (66 days). **Fig. 22** Kidney No. B-1 (71 days). **Fig. 23** Kidney No. S-13 (260 days)

Fig. 24 Kidney No. T-3 (338 days).

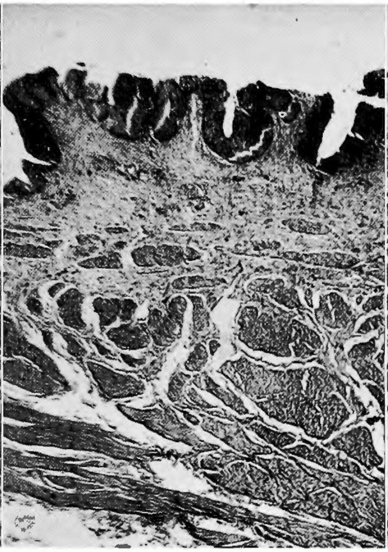

Fig. 25 Bladder wall No. S-5 (20 days).

Fig. 26 Bladder wall No. S-4 (88 days).

Fig. 27 Bladder wall No. B-2 (93 days).

Fig. 28 Bladder wall No. S-13 (260 days).

Fig. 29 Bladder neck No. S-15 Tetron : 33 days.

Fig. 30 Bladder neck No. B-8
Polyvinyl formal : 32 days.

Fig. 31 Bladder neck No. S-4
Tetron : 88 days.

Fig. 32 Bladder neck No. B-1
Polyvinyl formal : 71 days.

Fig. 33 Bladder neck No. S-8 Tetron : 123 days.

Fig. 34 Bladder neck No. S-25 Tetron : 59 days.

和文抄録

人工弁による膀胱括約筋再建の試み

京都大学医学部外科教室第2講座 (指導：青柳安誠教授)
浜 垣 仁

尿道再建の問題については，さきに教室の木村忠司助教授等が，回腸分節を利用する "Antepubic vesico-ileal neourethrostomy" なる術式を発表し，この方法によつて確実に欠損後部尿道を補填し得ること，さらに，恥骨上に尿道圧迫帯を使用することによつて，ある程度尿保持も可能なることを示した．

著者は，これに引き続き，膀胱括約筋を機能的に再建する目的で，数種の人工弁を作整し，これらを実験的に検討し，さらに臨床的に一患者に応用した．このような試みは未だ文献上見られない．

著者の作整した弁は，それ等の機能的な面から大別すると，Straight valve, Thin wall balloon valve およびThick wall balloon valve の三種類であり，いずれも合成樹脂，特に一部塩化ビニール製の弁を除けばすべて，現在最も組織反応の少いとされている医療用シリコーン・ゴムで作つた．

Straight valveは盲端に終る先端近くにSlit を作り，これが他端から加わる圧によつて自動的に開閉し弁として働くものである．一方，Thin wall balloon valve は Balloon の頂部にSlitを作り，この対側で Tube と連絡するもので，Balloon 表面に加わる圧によつて，Balloon の自動的変形およびその回復と共に，Balloon 上の Slit が開閉し弁機能を果すものである．さらに，Thick wall balloon valveは外観は先述のBalloon valve と同一であるが，Balloonの壁を厚くし，Balloon の変形すなわち Slit の開放・閉鎖を腹壁上から装作する弁装置である．

Straight valve では，弁の開放圧と閉鎖圧との間に圧差は得られなかつたが，Thin wall balloon valveでは，弁挿入後，ある膀胱内圧に達すると弁が開き排尿がみられ，排尿により膀胱内圧が低下しある内圧に達して始めて自動的に弁が閉鎖し排尿は終るという風にこの弁の開放圧と閉鎖圧との間に，ある圧差が得られたので，この点生理的膀胱括約筋機能に一歩近ずき得たかと考えられる．

実験的に，雌犬の膀胱頸部にこれらの弁を挿入・固定し長期間排尿状態を観察したが，Straight valve 群では17例中8例に，Thin wall balloon valve群では10例中7例に所期の目的が達せられた．Thick wall balloon valveは3例に応用し，その有効性を確認したが，弁の性質上この群では長期観察を行い得なかつた．

実験成功例・失敗例とも，生理学的また病理組織学的検索を行つたが，失敗例においてその最大の原因は，弁の膀胱内滑脱および，Balloon の永続的変形であつた．さらに，数例に尿結石の形成を認めたが，弁滑脱の原因となつた弁固定用テープの組織反応と共にいずれも使用した合成樹脂材料に対する異物反応が実験成績を左右するものであることを知つた．

臨床症例にたいしては，まず膀胱・後部尿道摘出後S字状結腸および回腸でそれぞれを代用・補填し，回腸・尿道吻合部に，動物実験の成績から最も安全・確実と思われたThick wall balloon valve を挿入した．術後，この弁はその目的を達していたが，その後回腸側圧および皮膚を含めて新尿道たる回腸周囲の瘢痕性収縮により，Balloon が変形し原形に復することができないので抜去せざるを得なかつた．

さらに壁の厚い Balloon valve を作れば臨床上応用可能と思われる．また，弁の挿入・固定方法が改良され，弁の交換が容易に行うことができれば，応用範囲はさらに拡大されるであろう．